UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALLAN LEPINE

Appeal No. 2005-1949
Application No. 09/829,168

ON BRIEF

Before GARRIS, FRANKLIN, and MOORE, *Administrative Patent Judges.*

MOORE, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) from the final rejection of claims 1 and 3-12. Claims 2 and 13-36 have been canceled. Thus, only claims 1 and 3-12 are before us on appeal.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claimed subject matter and reads as follows:

1. A method of providing nutrition to a critical care canine comprising:

administering to said canine an amount of an artificially produced canine milk substitute composition comprising, on a dry matter basis, from about 35 to 45% protein, from about 25 to 35% fat, and from about 10 to 25% carbohydrates; wherein said protein comprises casein and whey in a weight ratio of about 70:30.

The References

In rejecting the claims under 35 U.S.C. §102(b) and §103(a), the examiner relies upon the following references:

Fujimori	5,294,458	Mar. 15, 1994
Gil et al. (Gil)	5,709,888	Jan. 20, 1998
Meyer (European Patent)	EP 0 259 713 B1	Mar. 18, 1992

The examiner also relies upon the following "Admitted Prior Art" from the Specification of grandparent application 09/163,778, pages 1 and 5:

Specification, page 1, lines 8-11, discussing naturally occurring canine milk and the known formulation of replacement milk

Specification, page 5, lines 21-26, discussing the content of naturally occurring canine milk.

The Invention

The invention relates to the provision of nutrition to a critical care canine by administering to the canine an artificially produced canine milk substitute which includes, by weight of dry matter, from about 35 to 45% protein, from about 25 to 35% by weight fat, and from about 10 to 25% by weight

carbohydrates. The protein source comprises casein and whey in a weight ratio of about 70:30. (Claim 1)

II. The Rejections

The rejections at issue are as follows:

A) Claims 1 and 3-5 and 9 stand rejected under 35 U.S.C. §102(b) as anticipated by, or alternatively, under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art from pages 1 and 5 of the grandparent application 09/163,778.

B) Claims 7-9, 11 and 12 stand rejected under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art from pages 1 and 5 of the grandparent application 09/163,778.

C) Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable as obvious over the Admitted Prior Art as applied in Rejection A, further in view of Gil.

D) Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable as obvious over the Admitted Prior Art as applied in Rejection A, further in view of Gil.

E) Claims 1 and 9 stand rejected under 35 U.S.C. §102(b) as anticipated by, or alternatively under 35 U.S.C. §103(a) as obvious over, Meyer.

F) Claims 3-5, 11, and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable as obvious over the disclosure of Meyer.

G) Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Meyer as applied in Rejection E, further in view of Gil.

H) Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Meyer as applied in Rejection E, further in view of Fujimoro.

III. Discussion

A) The Rejection of Claims 1 and 3-5 and 9 under 35 U.S.C. §102(b) as anticipated by, or alternatively, under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art from pages 1 and 5 of the grandparent application 09/163,778.

The examiner has found that naturally occurring canine milk contains all of the elements of instant claim 1. The examiner therefore concludes that naturally occurring canine milk clearly anticipates the subject matter of claim 1. (Final Rejection, October 31, 2003, page 2, lines 24-26). The examiner urges that there is no patentable distinction between natural beagle milk and the claimed invention. (Examiner's Answer, page 3, last 3 lines).

Claim 1 recites a method including the administration of an amount of "an artificially produced canine milk substitute

composition". Claim 1 is therefore a method of using a product made by a process. The product made by this process has no limitations within the claim which distinguish the end product from natural beagle milk.

The appellant observes that claim 1 recites that the canine milk substitutes be "artificially produced." (Appeal Brief, page 5, lines 3-5).

These claims are written in product-by-process format, and as such are anticipated by a disclosure which is the same as a product made by the recited process, no matter how the reference product was made. *In re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).

Accordingly, we agree that the subject matter of claim 1 is anticipated by puppies feeding upon natural beagle milk. Anticipation under 35 U.S.C. Section 102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In this instance, the naked assertion that the milk is "artificially produced" does not overcome the anticipatory effect of natural beagle milk.

We therefore shall sustain the anticipation portion of this rejection.

Turning now to the alternative obviousness portion of the rejection, the examiner has found that it was known to formulate milk replacers to closely match the nutrient composition of canine milk. As a consequence, the examiner concludes, it would have been obvious to one of ordinary skill in the art to formulate a milk replacer with the composition of claim 1 to match the components of the natural beagle milk (Final Rejection, page 4, first 4 lines).

The appellant, on the other hand, urges that the present specification indicates that previous milk substitutes were formulated with limited data. Appellant's counsel states that it was the appellant's own work that led to the discovery of the detailed contents of natural beagle milk. (Appeal Brief, page 5, second and third paragraphs).

We observe that the appellant has substantially rewritten the specification to delete the detailed discussion of the components of natural beagle milk found in grandparent application 09/163,778. This deletion does not affect the inherent content of natural beagle milk for purposes of anticipation.

However, the Appellant has now explained that the previous study was an "investigative" study of natural milk. The resulting formulation was formulated from that data discovered by the appellant and preferably containing certain constituents in certain amounts and ratios (Specification, page 5, lines 10-15). The appellant therefore urges that this information was a result of its own investigation, not in the public domain, and its own work should not be used against him. (Appeal Brief, page 6, lines 1-11).

The Examiner does not address the appellant's position that this nonpublic work resulted in the formulation. Based upon this explanation, we find that on balance we agree with the appellant's position that the appellant's own work in investigating the composition of beagle milk should not be used against him in formulating an obviousness rejection. *In re Wertheim*, 541 F.2d 257, 269, 191 USPQ 90, 102 (CCPA 1976); see *In re Leslie*, 547 F.2d 116, 120, 192 USPQ 427, 430 (CCPA 1977).

The evidence of record in this case does not support the proposition that the nutrient profile as set forth by the appellant in its previous specification, was available to one of ordinary skill in the art at the time the invention was made. How, then, the previously unknown makeup of beagle milk could

have rendered the Appellant's claim obvious is not sufficiently explained by the Examiner.

Accordingly, and based upon the specific facts of this application, we reverse the obviousness portion of this rejection. We further reverse rejections (B), (C), and (D) which are based upon obviousness over the "Admitted Prior Art" for the same reason.

E) The Rejection of Claims 1 and 9 under 35 U.S.C. §102(b) as anticipated by or alternatively, under 35 U.S.C. §103(a) as obvious over, Meyer.

Claim 1 is as reproduced above. Claim 9 reads as follows:

9. The method of claim 1 in which said composition contains from about 4 to 8% by weight lactose.

The examiner has found that Meyer discloses feeding dogs an artificially produced canine milk substitute including 1-25% lactose, at least 25% fat, and 30% protein composed of casein and whey. (Final Rejection, page 5, last three lines).

The appellant has not challenged these findings.

The examiner has additionally found that Meyer discloses a casein/whey ratio of 5.0:2.1. (Final rejection, page 5, last line - page 6, line 1). Accordingly, the examiner has found Meyer anticipates the instant claims 1 and 9.

Any differences that may exist, the examiner concludes, would have been obvious.

In reviewing the Meyer reference, we find that it substantially supports the examiner's findings.

We make the following specific factual findings. Meyer describes the preparation of a synthetic milk substitute for dogs. (Meyer, page 1, translation, title; page 2, lines 24-25). That synthetic dog milk substitute has more than 30% protein, preferably between 31-40% (Meyer, translation, page 3, lines 24-25). Meyer's described range substantially overlaps the claimed about 35-45% protein range of claim 1.

Meyer also describes a synthetic dog milk substitute with a fat content of more than 25% fat, preferably from 25.5 to 40%. (Meyer, translation, page 4, lines 19-20). This range substantially overlaps the range of about 25 to 35% claimed in claim 1.

Meyer describes a synthetic dog milk substitute having less than 30% lactose, preferably from 1 to 25% lactose (Meyer, translation, page 3, lines 23-24). Lactose is a carbohydrate. This range substantially overlaps the claimed range of about 10 to 25% carbohydrate of claim 1, and encompasses the claimed range of about 4-8% lactose for dependent claim 9.

Additionally, Meyer describes the use of whey proteins, said to include beta-lactoglobulin, alpha-lactalbumin, serum albumin,

immunoglobulins, and protease-peptone (Meyer, translation, page 3, lines 28-34).

Meyer describes the use of milk proteins in the form of caseins including sodium potassium, calcium or acid caseins. (Meyer, translation, page 4, lines 5-6).

Meyer describes that the albumin-globulin [whey] ratio relative to the casein fraction is from 2.1 to 3.0:4.1 to 5.0. (Meyer, translation, page 4, lines 13-14). One endpoint of the ratio (2.1 whey:5.0 casein) is within the claim language of "about" 30% whey and 70% casein.

The Federal Circuit explained in *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367, 60 USPQ2d 1173, 1179 (Fed. Cir. 2001) that "like the term 'about,' the term 'substantially' is a descriptive term commonly used in patent claims to 'avoid a strict numerical boundary to the specified parameter,'" quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217, 36 USPQ2d 1225, 1229 (Fed. Cir. 1995). "[A]bout 70:30" therefore gives leeway around the endpoints of the claimed ratio of claim 1; which leeway overlaps the description of the casein:whey ratio in Meyer.

We therefore agree that the Examiner has established a prima facie case of anticipation vis-à-vis claims 1 and 9 by Meyer.

The appellant, on the other hand, relying on an excerpt from the Encyclopedia of Food Science, Food Technology and Nutrition, makes a single assertion against the case of anticipation. The appellant asserts as his sole argument against anticipation that sweet whey and acid whey have a crude protein content of 12.9% and 11.7%, respectively. Therefore, it is urged, the two proteins of whey cannot describe a total whey content and Meyer therefore does not disclose a casein:whey ratio of about 70:30. (Appeal Brief, December 20, 2004, page 8, lines 22-27).

We are not persuaded by this argument.

First, we observe that Meyer, the appellant's claims 1 and 9, and the appellant's specification all reference the protein content in percentages by weight. (Meyer, page 7, last line, Specification, page 2, lines 15-18). Meyer specifically describes what the appellant is claiming, in protein content, by weight.

The appellant urges that Meyer does not describe what he is claiming because page 4888 of the Encyclopedia gives, in table 1, the composition of sweet and acid whey powders as having 12.9 and 11.7 percent crude protein.

This contention is without merit. On the same page the appellant references, the Encyclopedia notes that "[c]learly the

composition of whey will vary considerably, depending on the source of the milk and the manufacturing process involved." (Page 4888, column 1, lines 29-31). One of ordinary skill in the art understands that whey has several components, including fat, protein, lactose, ash, nitrogen and water. (*Id.*) The references, and the claims, are discussing the protein content of whey.

Meyer expressly describes the ultrafiltration purification of whey over membranes to remove water, lactose, salts, and low molecular substances to retain whey proteins. (Meyer, sentence spanning pages 3 and 4). One of ordinary skill in the art would have understood this as describing that the whey can have different contents and Meyer expressly accounts for those in its examples. See, e.g. Meyer, page 5, line 25, which recites, in Example 1, "20% Whey protein with 1% lactose fraction." See also examples 2-5, which give raw protein percentages by weight.

Furthermore, both the claim and the reference do not speak to "total whey content" as argued by the appellant; rather, the claim recites that the protein comprises whey and the reference describes the underlying composition of whey.

Accordingly, we find that Meyer's description of a ratio of casein:whey with an endpoint of 70:30 does describe the appellant's claimed ratio of "about" 70:30.

As to the alternative obviousness rejection, to the extent that there is any difference between appellant's claims and the disclosure of Meyer we also observe that when the difference between the claimed invention and the prior art is the range or value of a particular variable, then a prima facie case of obviousness is properly established when the difference in the range or value is minor. Haynes Int'l., Inc. v. Jessop Steel Co., 8 F.3d 1573, 1577 n.3, 28 USPQ2d 1652, 1655 n.3 (Fed. Cir. 1993). Also, a claimed invention is rendered prima facie obvious by the teachings of a prior art reference that discloses a range that touches the range recited in the claim. In re Malagari, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).

Finally, Meyer teaches that the desired result of obtaining milk which can be used for practical feeding of carnivorous animal whelps is obtained by "[a]ccurately maintaining the content of essential amino acids and protein components and matching the fatty acid pattern to that of the mother's milk as much as possible." (Meyer, page 7, last paragraph). In other words, adjusting the content of the milk to achieve the method as claimed is a result-effective variable. It is not inventive to discover optimum or workable ranges by routine experimentation, and appellants have the burden of proving any criticality. *In re*

Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-19 (CCPA 1980); *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Hence, we determine that the limited range in Meyer renders obvious appellant's recited ratio in claim 1.

As a consequence, we agree with the examiner that (1) the reference discloses each claim limitation from claims 1 and 9, and (2) if there is any difference, the difference is minor and the recited ratio is a) obvious over the range disclosed in Meyer and b) simple optimization of a result-effective variable.

We therefore affirm this rejection as it relates to obviousness.

F. The Rejection of Claims 3-5, 11 and 12 Under 35 U.S.C. §103(a).

Claims 3-5, 11, and 12 stand rejected under 35 U.S.C. §103(a) as being unpatentable as obvious over the disclosure of Meyer.

Claim 3 reads as follows:

3. The method of claim 1, in which said composition comprises about 38% protein.

Claim 4 reads as follows:

4. The method of claim 1, in which said composition comprises about 28% fat.

Claim 5 reads as follows:

5. The method of claim 1 in which said composition comprises about 19% carbohydrates.

Claim 11 reads as follows:

11. The method of claim 1 in which said composition contains from about 27 to 37% by weight fatty acids.

Claim 12 reads as follows:

12. The method of claim 1 in which said composition contains from about 15 to 25% by weight essential amino acids.

The examiner has found that optimizing the amount of each component would require only routine experimentation by one reasonably skilled in the art. (Rejection, October 31, 2003, page 6, lines 5-6).

The Appellant has not contested this finding. Rather, the appellant asserts that the examiner has failed to provide any rationale for the rejection (Appeal Brief, page 9, lines 7-8). The appellant also points to 4 specific embodiments which do not fall within the claims as "antithetical". *(Id.)*.

We disagree. The examiner has observed, correctly, that this appears to be optimization of the content of each component. As noted above, where general conditions of the appealed claim are disclosed in the prior art, it is not inventive to discover

optimum or workable ranges by routine experimentation, and appellants have the burden of proving any criticality. *Boesch*, 617 F.2d at 276, 205 USPQ at 218-19; *Aller*, 220 F.2d at 456, 105 USPQ at 235.

We must consider whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention. See *In re Young*, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

As found above, Meyer describes synthetic dog milk substitute which has more than 30% protein, preferably between 31-40% (Meyer, translation, page 3, lines 24-25). Claim 3 recites "about 38%" protein. The appellant has not demonstrated why this limitation is critical or why the examiner is incorrect that this limitation reflects optimization by routine experimentation. Accordingly, we affirm this rejection as it relates to claim 3.

Meyer also describes a synthetic dog milk substitute with a fat content of more than 25% fat, preferably from 25.5 to 40%. (Meyer, translation, page 4, lines 19-20). Claim 4 recites "about 28%" fat. Again, the appellant has not demonstrated why this limitation is critical or why the examiner is incorrect that this limitation reflects optimization by routine experimentation.

Accordingly, we affirm this rejection as it relates to claim 4.

Meyer describes a synthetic dog milk substitute having less than 30% lactose, preferably from 1 to 25% lactose (Meyer, translation, page 3, lines 23-24). Lactose is a carbohydrate. Claim 5 recites "about 19%" carbohydrates. Again, the appellant has not demonstrated why this limitation is critical or why the examiner is incorrect that this limitation reflects optimization by routine experimentation. Accordingly, we affirm this rejection as it relates to claim 5.

Meyer describes the raw fat content of synthetic milk is preferably higher than 25%, and the preferred use of fatty acids, both short chain and long chain (page 4, lines 19-22). Claim 11 recites "about 27 to 37%" by weight fatty acids. Again, the appellant has not demonstrated why this limitation is critical or why the examiner is incorrect that this limitation reflects optimization of the amount or type of fat by routine experimentation. Accordingly, we affirm this rejection as it relates to claim 11.

Meyer describes that, to compensate for the potential natural variation in the raw protein component, it is useful to add pure amino acids including methionine, lysine, and cystine. (page 4, lines 15-16). The target protein concentration is more

than 30% and preferably 31 to 40% (page 3, lines 24-25). Methionine, lysine, and cystine are known indispensable amino acids. Claim 12 recites "about 15 to 25%" by weight essential amino acids. Again, the appellant has not demonstrated why this limitation is critical or why the examiner is incorrect that this limitation reflects optimization of the amount or type of amino acid by routine experimentation guided by Meyer's description. We therefore affirm this rejection as it relates to claim 12.

G) The Rejection of Claim 6 Under 35 U.S.C. §103(a)

Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Meyer as applied in Rejection E, further in view of Gil.

Claim 6 of the present application reads as follows:

6. The method of claim 1 in which the source of fat is selected from the group consisting of corn oil, canola oil, butter oil, arachidonic acid, docosahexaenoic acid, and blends thereof.

The examiner has found that Gil teaches a preferred source of fat in human milk replacer is a corn oil (column 10, line 64) and weanling rats may be fed arachidonic and docosahexaenoic acid as fats. (Office Action, October 31, 2003, paragraph 5 spanning pages 4-5).

The appellant urges that the examiner has not provided a rationale for combining Meyer and Gil, nor constructed an argument based on the combination (Appeal Brief, page 9, lines 17-20). We disagree. First, when the references are all in the same or analogous fields, knowledge thereof by the hypothetical person of ordinary skill is presumed, *In re Sernaker*, 702 F.2d 989, 994, 217 USPQ 1, 5 (Fed. Cir. 1983). In the present instance, all the cited references are in the field of milk replacers. Perusal of the references indicates that they are in the same type of field and would commend themselves to the attention of one of ordinary skill in the art. The appellant has put forth no reasons why this would not be so or the combination is improper.

Rather, the appellant urges that Gil relates to fat mixtures for human nutrition and there is no "disclosure, connection, or even suggestion" in Gil to substitute any of the fat mixtures into an artificial canine milk substitute or modify the casein and whey ratios. (Appeal Brief, page 10, lines 1-2).

First, Gil is relied upon for a teaching of fat substitutes, not the casein and whey ratios. Second, the appellant's argument assumes that one of ordinary skill has no skill. We do not presume the artisan to be lacking any basic skills. See *In re*

Sovish, 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985). One of ordinary skill in the art readily understands Gil to suggest substitution of fat sources.

We therefore affirm this rejection.

H) The Rejection of Claim 10 Under 35 U.S.C. §103(a)

Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Meyer as applied in Rejection E, further in view of Fujimoro.

Claim 10 of the present application reads as follows:

10. The method of claim 1 in which said composition contains about 0.50% by weight fructooligosaccharide.

The examiner has found that Fujimori describes fructooligosaccharides are known to be in pet foods to reduce objectionable odors in pet wastes. Accordingly, the Examiner concludes it would have been obvious to use fructooligosaccharides in the canine milk replacer to obtain its known benefits. (Office Action, October 31, 2003, page 5, paragraph 6).

The appellant urges that the examiner has not provided any rationale for the combination of Fujimori with Meyer, and has not constructed an argument based on this combination (Appeal Brief, page 10, lines 8-11).

This argument is without merit. The examiner has stated a rationale for combining the references, and has constructed an argument as noted above. We find no error in combining Fujimori with Meyer as both are related to pet nutrition and Fujimori discloses several advantages of oligofructosaccharides in pet foods including keeping intestines in good order and deodorizing unpleasant odors (column 1, lines 5-11).

The appellant argues that Meyer fails to disclose or even suggest the use of artificially produced canine milk substitutes comprising casein and whey at a weight ratio of 70:30. (Appeal Brief, pages 10, 12-14). The argument is the same made by the appellant for rejection E and has been addressed above. It remains unpersuasive for the reasons noted above.

Finally, the appellant urges that Fujimoro fails to suggest any modification to a casein and whey ratio in Meyer and fails to suggest inclusion of a fructooligosaccharide in an artificially produced canine milk substitute. (Appeal Brief, page 10, last paragraph). This argument is without substantive merit. First, Fujimoro is not relied upon for a teaching of a casein to whey weight ratio. Second, Fujimoro need not specifically suggest use of fructooligosaccharides in an artificially produced canine milk substitute; rather, it is the combination of the prior art which

must suggest the use of the fructooligosaccharide in the canine milk substitute. The examiner has pointed to the benefits of fructooligosaccharide in pet food, and concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to transfer those benefits to the artificially produced milk as recited in the claims. We find no error in the examiner's conclusion. Accordingly, we affirm this rejection.

Summary of Decision

The rejection (A) of claims 1 and 3-5 and 9 under 35 U.S.C. §102(b) as anticipated by the Admitted Prior Art from pages 1 and 5 of the grandparent application 09/163,778 is affirmed.

The rejection (A) of claims 1 and 3-5 and 9 under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art from pages 1 and 5 of the grandparent application 09/163,778 is reversed.

The rejection (B) of claims 7-9, 11 and 12 under 35 U.S.C. §103(a) as obvious over the Admitted Prior Art from pages 1 and 5 of the grandparent application 09/163,778 is reversed.

The rejection (C) of claim 6 under 35 U.S.C. §103(a) as being unpatentable as obvious over the Admitted Prior Art as applied in Rejection A, further in view of Gil is reversed.

The rejection (D) of claim 10 under 35 U.S.C. §103(a) as being unpatentable as obvious over the Admitted Prior Art as applied in Rejection A, further in view of Gil is reversed.

The rejection (E) of claims 1 and 9 under 35 U.S.C. §102(b) as anticipated by, or alternatively under 35 U.S.C. §103(a) as obvious over, Meyer is sustained.

The rejection (F) of claims 3-5, 11, and 12 under 35 U.S.C. §103(a) as being unpatentable as obvious over the disclosure of Meyer is sustained.

The rejection (G) of claim 6 under 35 U.S.C. §103(a) as being unpatentable over Meyer as applied in Rejection E, further in view of Gil is sustained.

The rejection (H) of claim 10 under 35 U.S.C. §103(a) as being unpatentable over Meyer as applied in Rejection E, further in view of Fujimoro is sustained.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

BRADLEY R. GARRIS)
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)
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